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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,838	04/20/2004	Stephanie M. Kladakis	022956-0261	5281
21125 7590 03/12/2009 NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604				
EXAMINER				
WOODWARD, CHERIE MICHELLE				
ART UNIT		PAPER NUMBER		
1647				
NOTIFICATION DATE		DELIVERY MODE		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

doctet@nutter.com

Office Action Summary

Application No.

10/828,838

Applicant(s)

KLADAKIS ET AL.

Examiner

CHERIE M. WOODWARD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10-14, 16-21, 23-27 and 29-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-14, 16-21, 23-27 and 29-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Formal Matters

1. Applicant's Remarks filed 1/6/2009 are acknowledged and entered. Claims 1-8, 10-14, 16-27, and 29-33 are pending. Claims 9, 15, 22, 28, and 34 have been cancelled by Applicant. Claims 29-31 remain withdrawn as being drawn to non-elected inventions. Claims 1-8, 10-14, 16-21, 23-27, and 32-33 are under examination.

Response to Arguments

Claim Rejections Maintained

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1-8, 10-14, 16-21, 23-27, and 32-33 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Bowman et al. U.S. Patent Publication US 20020127265 (12 September 2002) and Huckle et al., WO 01/85226 (published 15 November 2001), as exemplified by Boland et al., (J Macromol Sci –Pure Appl Chem. 2001;A38(12):1231-1243), for the reasons of record and the reasons set forth herein.

Applicant argues that the examiner appears to rely on the lower standard required to shift the burden of proof to Applicants for product-by-process claims (Remarks, p. 2, fourth paragraph). Applicant argues that the examiner has not met the examiner's burden of developing reasons supporting on a

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reliance of inherency (Remarks, p 2, last paragraph). Applicant argues the holding in *In re Rijckaert* that the mere fact that a certain thing may result from a given set of circumstances is not sufficient to establish inherency by probabilities or possibilities (Remarks p. 3, first paragraph). Applicant argues that the mere fact that Bowman may have the claimed modulus of elasticity is not sufficient to establish the inherency thereof and that the examiner's reliance on inherency is unsupported and improper (Remarks, p. 3, second paragraph). Applicant argues that the examiner's statements that Bowman sets forth a strain requirement is incorrect and that neither tensile strength nor tear strength are a strain requirement (Remarks, p. 3, third paragraph). Applicant argues that in the absence of a strain requirement, modulus of elasticity, which is the ratio of stress to strain, cannot be calculated (Remarks, p. 3, third paragraph). Applicant argues that the values disclosed by Bowman are merely the properties of the elastomeric copolymers themselves and there is no teaching or suggestion that Bowman's polymeric foam has the same properties as the raw polymers (Remarks, p. 3, third paragraph). Applicant argues that the examiner's arguments regarding the obviousness of the claimed density range are unclear (Remarks, p. 3, last paragraph). Applicant argues that the examiner has failed to establish a *prima facie* case as to the claimed density range, citing MPEP 21102.01(I) (Remarks, p. 4, first paragraph). Applicant argues that the claimed nonwoven polymeric material is not equivalent to the materials disclosed by Bowman (Remarks, p. 4, second paragraph). Applicant argues that the term non-woven does not include open knitted mesh material, which is a preferred embodiment of Bowman and that Bowman also does not teach or suggest that the mesh material has a density in the claimed range (Remarks, p. 4, second paragraph).

Applicant's arguments have been fully considered, but they are not persuasive. Applicant's argument that that the examiner appears to rely on the lower standard required to shift the burden of proof to Applicants for product-by-process claims is spurious where the claims are clearly composition of matter claims.

Regarding Applicant's argument that that the examiner has not met the examiner's burden of developing reasons supporting on a reliance of inherency and that the burden of proof only shifts to Applicant when the claimed and prior art products are identical or substantially identical or are products, the examiner has already set forth a detailed explanation and rationale for why, absent evidence to the contrary, the claimed subject matter and the composition of the prior art are inherently substantially identical.

In attempting to rebut the examiner's *prima facie* case of obviousness, Applicant is relying on the silence of the art regarding to two inherent physical properties of the prior art to meet the *quid pro quo* standard of patentability. The examiner has stated of record that the two properties at issue are inherent

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physical properties that are readily testable. In spite of the repeated requests by the examiner for Applicant to provide any evidence or data distinguishing Applicant's claimed invention over that of the recited prior art, Applicant has chosen to present only attorney argument. The examiner has also previously stated of record that, as a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith (see *In re Brown*, 173 USPQ 685, 688 (CCPA 1972)). The claiming of an unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 195 USPQ 430, 433 (CCPA 1977).

The Patent Office can require Applicant to prove that subject matter shown to be in prior art does not possess characteristic relied on where it has reason to believe that functional limitation asserted to be critical for establishing novelty in claimed subject matter may be inherent characteristic of prior art; this burden of proof is applicable to product and process claims reasonably considered as possessing allegedly inherent characteristics (*In re Best*, at 433). *In re Best* also holds that the Patent and Trademark Office can require applicant to prove that prior art products do not necessarily or inherently possess characteristics of his claimed product where claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes. In such cases, the burden of proof is on Applicant (*Id.* at 433, citing the burden of proof required to overcome an inherency rejection). See also, *In re Spada*, 911 F.2d 705, 708, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990) (holding that when the PTO shows sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not).

Regarding Applicant's argument directed to the holding in *In re Rijckaert* that the mere fact that a certain thing may result from a given set of circumstances is not sufficient to establish inherency by probabilities or possibilities, Applicant's argument is not well taken and it does not serve to advance prosecution. A patent Applicant is free to recite features of a composition of matter either structurally or functionally. See *In re Swinehart*, 439 F.2d 210, 212, 169 USPQ 226, 228 (CCPA 1971). The CCPA stated in *Swinehart*, "where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on" (439 F.2d at 213, 169 USPQ at 228). See also, *In re Ludtke*, 441 F.2d 660, 663-64, 169 USPQ 563, 565-67 (CCPA 1971). In the instant case, all of the positive limitations of the claimed method are expressly disclosed in the prior art references except for the modulus of elasticity and suture pull-out strength of the product used (see Office Actions mailed

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5/4/2007, pp. 8-12; 12/31/2007; and 10/16/2008). The examiner's statements that those parameters/functions of the claimed composition, which are recited in the instant claims but are not expressly disclosed in the prior art reference, would be inherent is a reasonable one, absent evidence to the contrary. Applicants have not presented any evidence to contradict the examiner's position, in spite of multiple invitations to provide data or evidence. The examiner has pointed to structural evidences of physical properties of the compositions disclosed in the references themselves and evidentiary references that also show the properties of the compositions. Applicant is reminded that it is well known in the art that tensile strength is dependent on the concentration of the polymer comprising the composition (see, for exemplary purposes only, Boland et al., *supra*, pp. 1240, Chart 3; p. 1241, Chart 4, paragraph two, and Chart 5; previously cited of record in the Office Action of 5/4/2007, at p. 9). Although Applicants have urged that the properties of the instantly claimed meniscal repair device are unique, they have offered no comparison of those properties with the corresponding parameters of Bowman and Huckle's products.

Regarding Applicant's arguments that the examiner's arguments regarding the obviousness of the claimed density range are unclear and that the examiner has failed to establish a *prima facie* case as to the claimed density range. The examiner clearly and unambiguously stated in the Office Action mailed 10/16/2008 (page 4, second paragraph) that density limitations within the claimed range of 120 mg/cc (taught in units of mg/cm³) are taught by the '226 publication at page 21, line 34.

Regarding Applicant's argument that the values disclosed by Bowman are merely the properties of the elastomeric copolymers themselves and there is no teaching or suggestion that Bowman's polymeric foam has the same properties as the raw polymers, Applicant's attention is directed to *In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963). In *In re Papesch*, the Court held "[f]rom the standpoint of patent law, a compound and all of its properties are inseparable; they are one and the same thing. The graphic formulae, and the chemical nomenclature, the systems of classification and study such as the concepts of homology, isomerism, etc., are mere symbols by which compounds can be identified, classified, and compared. But a formula is not a compound and while it may serve in a claim to *identify* what is being patented, as the metes and bounds of a deed identify a plot of land, the *thing* that is patented is not the formula but the compound identified by it." A *prima facie* case of obviousness may be made when chemical compounds have very close structural similarities and similar utilities. "An obviousness rejection based on similarity in chemical structure and function entails the motivation of one skilled in the art to make a claimed compound, in the expectation that compounds similar in structure will have similar properties." *In re Payne*, 606 F.2d 303, 313, 203 USPQ 245, 254 (CCPA 1979). See also, *In re Papesch*,

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315 F.2d 381, 137 USPQ 43 (CCPA 1963) and *In re Dillon*, 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1991).

Regarding Applicant's argument that the present invention uses a "non-woven" material that is entirely different from an embodiment of Bowman which teaches a low density or open knitted mesh material, Applicant is selectively picking and choosing from various embodiments taught in Bowman. Applicant's attention is drawn to the totality of the teachings of Bowman, taken as a whole, which teach scaffold compositions comprising bioabsorbable polymeric foam having pores with an open cell structure that is joined or reinforced by a material to contribute enhanced mechanical and handling properties (Bowman, p.2, paragraph 23 and p. 4, paragraph 42), non-woven biocompatible bioabsorbable reinforcing material (Bowman, p. 4, paragraph 38), nonwoven reinforcing material comprising synthetic polymeric blends of polylactides and glycolides (Bowman, pp. 2-3, paragraph 28; and p. 4, paragraph 40), and nonwoven fibrous fabric (Bowman, p. 8, paragraph 74; Example 4, pp. 10-11, paragraphs 106-110). Additionally, as discussed at length in the prior office actions, Huckle et al., teach dry laid nonwoven material for use as tissue scaffolds at p. 11 Example 7, pp. 20-23, teach dry laid nonwoven yarn produced by feeding it into a stuffer box type crimping unit (p. 20, line 35 to p. 21, first paragraph). Tissue scaffolds fashioned from nonwoven material that can be bioresorbable or nonbioresorbable (p. 3, lines 30-34; p. 9, lines 29-31). Synthetic polymers comprising polylactides, polyglycolides, and polydioxanone are taught at p. 8, lines 34-35 (see also, p. 3, last paragraph to p. 4, first paragraph). Random entanglement is taught as providing a large surface area for cell attachment or capture during cellular in-growth (p. 11, lines 26-27). Huckle et al., teach dry-laid nonwoven scaffolds that provide superior strength for the implant.

Regarding Applicant's argument that the examiner has failed to present a *prima facie* case of obviousness, Applicant argues that the burden of proof only shifts to Applicant when the claimed and prior art products are identical or substantially identical or are produced by identical or substantially identical processes. As previously stated of record, it would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to combine the teachings of Bowman et al., and Huckle et al., to produce a biocompatible scaffold comprising a nonwoven polymeric material from dry laid polymer to provide increased suture-pull out strength. Additionally, Huckle et al., teach that random entanglement in the nonwoven scaffold provides a large surface area for cell attachment or capture during cellular in-growth. One of skill in the art reasonably would have expected success because Huckle et al., teach dry-laid nonwoven scaffolds used in that provide superior strength for the implant. The methods of producing the nonwoven components, whether by a wet lay process (i.e. electrospinning)

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or by a dry laid process, are taught as equivalents by Huckle et al., and thus, one would reasonably expect to produce a strong scaffold using either or both processes.

Regarding Applicant's arguments that the examiner's statements that Bowman sets forth a strain requirement is incorrect and that neither tensile strength nor tear strength are a strain requirement and that in the absence of a strain requirement, modulus of elasticity, which is the ratio of stress to strain, cannot be calculated, as previously stated of record, the concern of the examiner regarding the modulus of elasticity is directed to inherent intrinsic physical properties of the composition. The absence of explicit strain measurements in the '265 publication does not obviate the examiner's argument, where the physical property in question is testable. The examiner previously directed Applicant to paragraph 31 of the '265 publication which recites "[i]n addition to these elongation and modulus properties, suitable elastomers should also have a tensile strength greater than about 500 psi, preferably greater than about 1,000 psi, and a tear strength of greater than about 50 lbs/inch, preferably greater than about 80 lbs/inch." Because the modulus of elasticity is the ratio of stress to strain, the '265 publication provides sufficient evidence to suggest that, absent evidence to the contrary, the scaffolds taught therein would likely have a modulus of elasticity "greater than about 1.5MPa," based on the stress and strain requirements set forth in the '265 publication. If Applicant knows of or has reason to believe that the physical properties of the compositions taught in the prior art are not present in the instantly claimed composition, then Applicant should provide evidence or data establishing the difference. Applicant has provided no evidence to support the hypothesis that paragraph 31 of Bowman suggests that the modulus of elasticity of the elastomers disclosed by Bowman would be lower than the claimed range (Remarks, p. 9, first paragraph). As previously stated of record, Applicant is in the best position to provide the required data and evidence and the case law clearly states that the burden is on the Applicant to provide the required data/evidence. However, the examiner has provided evidence in the art (cited of record) that the modulus of elasticity (the ratio of stress to strain) is a testable physical property of a composition. The examiner has stated that the USPTO does not have the facilities available to run a modulus of elasticity test on the scaffold of the prior art and the instantly claimed scaffold and compare and contrast the differences. The examiner has stated that the burden is on Applicant to provide data or evidence that the modulus of elasticity of the prior art scaffold would not meet the limitations of the instant claims. See *In re Brown*, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (CCPA 1972) (holding at 1041, "[a]s a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith") and *Ex parte Gray*, 10 USPQ 2d 1922, 1924-25

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(PTO Bd. Pat. App. & Int.). Instead of Applicant providing data or evidence, the examiner has only been presented with attorney argument that has not served to advance prosecution.

Provisional Obviousness-Type Double Patenting Rejections

5. Claims 1-8, 10-14, 16-27, and 32-33 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14, 17-29, and 32 of copending Application No. 11/427,477, for the reasons of record. Applicant has stated that appropriate terminal disclaimers will be filed if warranted (Remarks, p. 5, second paragraph).

6. Claims 1, 7, 10-14, 19, and 24-27 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 8-11 of copending Application No. 11/856,743, for the reasons of record. Applicant has stated that appropriate terminal disclaimers will be filed if warranted (Remarks, p. 5, second paragraph).

7. Claims 1, 7, 8, 19, 24-27, 32, and 33 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5, 7-9, 12, and 13 of copending Application No. 11/856,741, for the reasons of record. Applicant has stated that appropriate terminal disclaimers will be filed if warranted (Remarks, p. 5, second paragraph).

Conclusion

NO CLAIM IS ALLOWED.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERIE M. WOODWARD whose telephone number is (571)272-3329. The examiner can normally be reached on Monday - Friday 9:30am-6:00pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cherie M. Woodward/
Primary Examiner, Art Unit 1647